A collaborative research system for functional outcomes following wartime extremity vascular injury

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Vascular injury with hemorrhage and ischemia is a significant cause of battlefield morbidity (i.e., amputation) and mortality.[1] Recent reports have demonstrated the rate of vascular injury in modern combat to be five times that reported in previous wars.[2–5] As a result of the volume of vascular trauma incurred, management of these injury patterns is of special importance. Indeed, approaches to vascular trauma (extremity and torso) have witnessed significant changes during the course of the current wars of Iraq and Afghanistan.[6,7] Therefore, an appraisal of long-term functional outcomes is warranted.

Limb salvage after extremity vascular injury has evolved through previous conflicts, benefiting from individual surgeons' experiences, backed by epidemiologic studies with subsequent technique development, application, and refinement.[1–3,6,7] As the most common injury pattern in combat,[8,9] extremity trauma leads to significant morbidity in the years after wounding. Although historical estimates reported early anatomic limb salvage rates (i.e., limb present or not),[1–3,6,7] the burden of injury from the Global War on Terror (GWOT) has led to a reappraisal of management strategies, including an emphasis on improving long-term functional outcome. Within civilian data systems, long-term management of vascular trauma is consistently plagued by a relative paucity of adequate follow-up, and the military experience has largely been absent since reports from Vietnam.[8,9]

A shift toward patient-based outcome studies after extremity injury was initiated in the civilian setting through the Lower Extremity Assessment Project (LEAP).[10] This study identified no significant differences between those undergoing limb salvage and amputees based on injury characteristics or the presence of a limb. In contrast, analysis from LEAP suggests that the factors most likely to influence functional outcome are preinjury social characteristics, such as level of education, income, and access to health care.

The Joint Theater Trauma System (JTTS) and associated Joint Theater Trauma Registry (JTTR) have afforded the opportunity to maintain faithful, demographic, and clinical records of the care provided to wounded warriors of the current wars of Iraq and Afghanistan. This database has potentiated the long-term follow-up of casualty care, making patient-based studies substantially more feasible.

Despite the recognized significance of the LEAP and similar studies that focus on functional outcomes after extremity vascular injury, there is no coordinated national system. To understand the relationship between early management strategies and limb outcome, a mechanism for patient-based assessment is required. The objective of this article was to introduce a system through which casualty-based outcomes can be ascertained following wartime extremity vascular injury, which in essence is to move on from simple binary outcome data into quality metrics.

KEY WORDS: Vascular; injury; limb; function; outcome; military; trauma; quality of life; SF-36; SMFA.

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PATIENTS AND METHODS

Casualty Identification

The GWOT Vascular Injury Initiative (GWOT-VII) was approved by the US Army Medical Research and Material Command Institutional Review Board. Casualties are identified using the JTTR, which is one facet of the JTTS. The JTTR and JTTS are held and maintained at the US Army Institute of Surgical Research and Joint Battlefield Health Institute at Fort Sam Houston, Texas, primarily as an instrument for performance improvement. The JTTR includes demographic and injury information on US troops acquired at all levels of combat casualty care in GWOT, including those injured in Operation Iraqi Freedom, Operation Enduring Freedom, and Operation New Dawn. The initial JTTR search criteria are detailed in Table 1. Data quality and continuity are assured and maintained by specialist nurses who review clinical documentation including multiple electronic charting systems such as the Patient Administration Systems and Biostatistics Activity database, the Theater Medical Data Store, and the Armed Forces Health Longitudinal Technology Application. Pertinent perioperative details are entered in the GWOT-VII database (Table 2, Oracle). Within this cohort, extremity vascular injuries are confirmed, and method of management (primary amputation, ligation, repair, etc.) was recorded. When discrepancies occur, the information is fed

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TABLE 1. Initial JTTR Search Criteria

JTTR Inclusion Criteria
Active duty injury
Injury sustained in battle (OIF/OEF/OND)
Vascular injury (AIS score, 2 6)
Vascular ICD-9
No concomitant head injury
March 2002 to August 2011

AIS, Abbreviated Injury Scale; ICD-9, DRG International Classification of Diseases 9th Rev; OEF, Operation Enduring Freedom; OIF, Operation Iraqi Freedom; OND, Operation New Dawn.

back to the JTTR, providing an additional layer of quality assurance. The same specialist nurses conduct direct patient contact and interviews; this further corroborates medical details. Figure 1 describes the process of data acquisition.

Patient Interview

Patients enrolled into the GWOT-VII database undergo contact information verification by the Defense Enrollment Eligibility Reporting System. If Defense Enrollment Eligibility Reporting System contact information is incorrect, commercial search engines and online armed forces e-mail account directories (e.g., Defense Knowledge Online) are used. Contact is initially made via telephone. If unavailable or unsuccessful, an e-mail is sent to the patient's listed e-mail address. If there is no response, repeated contact is attempted after a waiting period of 60 days.

After contact by the Research Nurse Coordinator (RNC), the subject is informed via a standardized script of both the purpose of the study and the risks/benefits. Standardized methods of informed consent (verbal/telephone or electronic) are obtained, and the subjects are subsequently enrolled in the study.

Once enrolled, the subject is counseled by the RNC on the importance of adequate medical follow-up and is offered the opportunity to receive a copy of their theater medical records through medical release forms (DD Form 2870). Standardized and validated surveys evaluating health-related quality of life and limb are delivered to the subjects via telephone, e-mail/Web link (Survey Monkey), paper copy or in person depending on the subject's preference. These include the Short Form 36 (SF-36), the Short Musculoskeletal Function Assessment (SMFA), and an independent group demographic questions specific to our study. A total of 99 questions are included in the questionnaires (36 from SF-36, 46 from SMFA, and 17 from the independent demographic questions).

Definition of Amputation

For this system to function optimally, terms must be specifically defined. Within this system, amputations are defined as major transtibial, or above the ankle, in the lower extremity and above the forearm in the upper extremity. Secondary amputations are defined as amputations performed during operations subsequent to an initial attempt at limb salvage, including repair of extremity vascular injury. Secondary amputations are further defined as early (≤30 days) and late (>30 days).

RESULTS

After the interim JTTR interrogation for vascular injuries (designated by either DRG International Classification of Diseases—9th Rev. or Abbreviated Injury Scale codes), 3,255 patients were identified. At interim analysis data lock

TABLE 2 . GWOT-VII Patient Information and Database Setup

Patient Information
Demographics
Name
Date of birth
Rank
Sex
Branch of service
Reason for noninclusion
Age (at injury)
Commission status
Injury data
Injury date
Injury mechanism
Amputation (1°)
Casualty operation
Associated injury
Injury cause
Coding (AIS score, ISS)
Vascular injury detail
Injury description
Repair
NPWD details
Prerepair
Associated injury
Complications
MESS
Ortho/nerve injury detail
Associated soft tissue
Repair
Associated bone injury
Complications
Associated nerve injury
Pretreatment/posttreatment
Anticoagulation
Transfusion requirements
Diagnostics
Initial vascular examination
Initial radiographic evaluation
Follow-up
Vascular examination
Radiographic evaluation

AIS, Abbreviated Injury Scale; ISS, Injury Severity Score; MESS, Mangled Extremity Severity Score; NPWD, negative pressure wound dressing.

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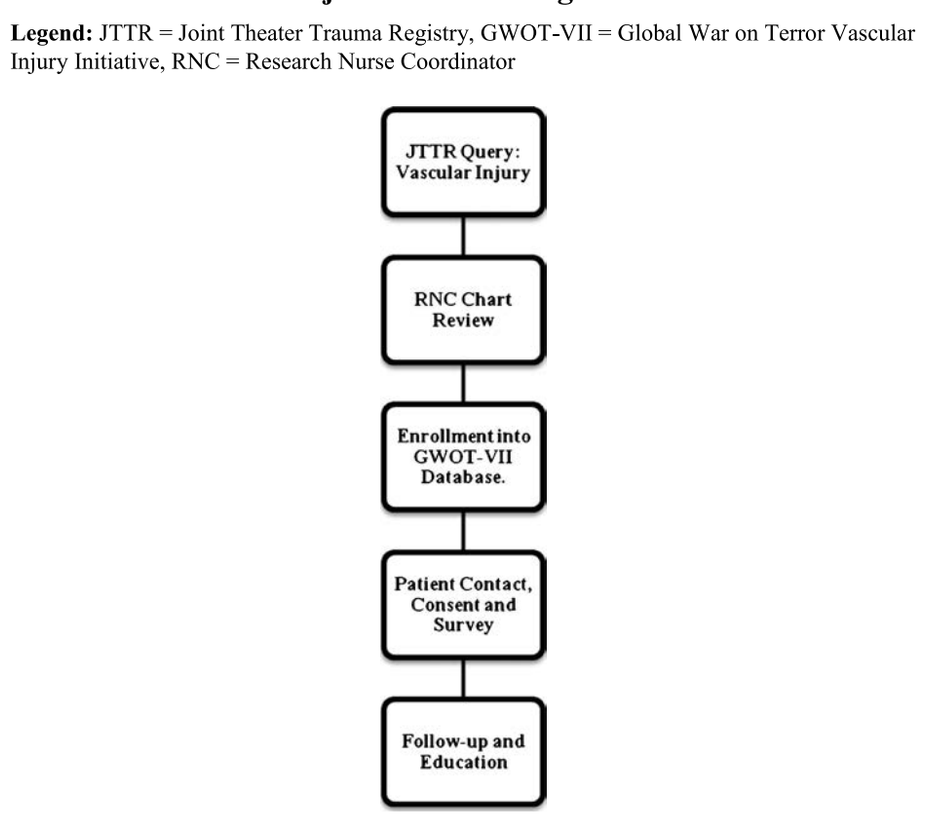

Figure 1. Subject inclusion algorithm.

(31 January 2012), 1,947 (60%) of 3,255 had been reviewed by the RNC team. Of the charts reviewed, 820 (42%) of 1,947 had confirmed extremity vascular injuries. Of these, 724 (87%) of 820 patients have had attempts at contact, with success in 395 of 820 (55%) and consent in 375 (95%) of 395. At interim analysis, 188 (50%) of 375 had completed all surveys.

The average number of phone contacts with consenting subjects before survey completion was 2.1 (range, 1–6). As depicted in Figure 2, the most common form of survey requested was via e-mail/Web link. Of the 245 who requested e-mail/Web link, 138 (56%) have completed the survey. Of those who requested telephone or in-person (28 and 1, respectively) as a mode of survey, all had nearly 100% completion rate. Currently, the mean time to follow-up is 62 months (range, 7–116 months) from time of injury to survey completion.

After contact, 20 (5%) have declined consent with the most common reason given being that the subject was "not interested." Of note, all individuals who consented to the survey portion of the study have also consented to future contact (including additional surveys).

DISCUSSION

Joint Theater Trauma Registry

The JTTS and associated JTTR have proven instrumental in many epidemiologic and short-term outcome–based studies in myriad patterns of injury including vascular, traumatic brain, urologic, and craniofacial injuries.[11–14] However, this is the first system to take the next step and gather follow-up, patient-based outcomes data through direct contact and combine it with acute injury and management information. The extended utility of the data system described here is to provide long-term follow-up information on particular injury patterns and their associated management regimens. Although this description applies primarily to combat-related injuries, it can also be extended to civilian trauma data registries (e.g., National Trauma DataBank).

Chart Review

The chart review process is a time and labor-intensive process owing to the large cohort of patients sustaining vascular injuries in our study population. Within the military charting systems, combat-related patient medical records contain information across all levels, or echelons of care, from austere prehospital level 1 management to comprehensive level 5 institutions. Medical information within these systems (Patient Administration Systems and Biostatistics Activity, Theater Medical Data Store, and Armed Forces Health Longitudinal Technology Application) is often concise or abbreviated. As a result, RNCs with deployment experience prove invaluable when navigating the charts because they have previous experience entering this information into these

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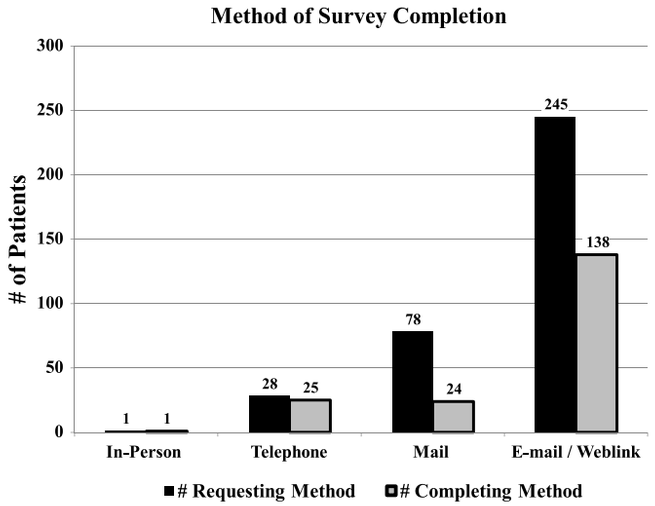

Figure 2. Method of survey completion.

same charting systems and understand associated nuances and peculiarities. The JTTR interrogation identified 3,255 potential subjects. After approximately 23 months, 60% of these subjects' charts had been reviewed, highlighting the time-consuming nature of the process (each chart review will require approximately 2 man-hours). A team of at least 2 to 4 full-time research nurse coordinators is required for a study of this magnitude.

GWOT-VII Database

The chart review from this search has resulted in the creation of the GWOT-VII database.[15] Like other traumatic vascular databases, this repository of patient information from combat-related vascular injuries has provided an opportunity to characterize the epidemiology and management of particular vascular injuries (such as extremity vascular injuries) sustained in a traumatic environment.[9,10] Modeled and expanded from the Vietnam Vascular Registry and the Balad Vascular Registry, this database will continue to provide information for quality control and ultimately optimized care for combat casualties.

Survey

In an endeavor to characterize the human experience with chronic disease/states after injury, quality of both life and limb requires critical evaluation. To meet these goals, the SMFA and SF-36 were used.

The SF-36 allows a practical and adequate cross-sectional evaluation with breadth to cover overall functional status. Consisting of 36 multiple-choice questions, the results are categorized into eight distinct scales meant to describe a patient's well-being. Four scales contribute to a Physical Component Summary score and four scales contribute to a Mental Component Summary score. The SF-36 was used in preference to other quality of life questionnaires, such as the Sickness Impact Profile and Nottingham Health Profile, because there is evidence from occlusive vascular disease studied that the SF-36 is superior in assessing the psychometric properties associated with intermittent claudication. We consider the symptom profile likely to be experienced by those with limb salvage to be more translatable to a chronic process like intermittent claudication, rather than severity of acute ischemia, for which the Nottingham Health Profile has proven more discriminatory.[16] Because SF-36 is based on a mean for the general population, it is not clear how absolute scores of young military personnel should be interpreted after injury. Steps to characterize the baseline SF-36 scores of military personnel would be a worthwhile pursuit to improve the validity of conclusions from this data and research endeavors in other injury profiles.

The SMFA was adapted by Engelberg et al.[17] from the longer established Musculoskeletal Function Assessment. Consisting of 46 multiple-choice questions, this questionnaire seeks to detail patient-based outcomes with particular emphasis on extremity pathology and injury. Similar to the SF-36, the SMFA consists of two descriptive scores. The bother index consists of 12 items that assess the degree to which a patient is mentally bothered in recreation, leisure, sleep and rest, work, and family. The dysfunction index assesses the patient's perception of physical impairment in four categories: daily activities, emotional status, limb function, and mobility.[1–3,6–8] Although published data currently focus primarily on musculoskeletal disorders, injuries, and postsurgical states, there is clear translatable value to combat-related extremity vascular injuries as well.[17–21]

Limiting bias from nonresponse is often the crux of long-term outcome–based data when surveys are required. Based on previous literature, this study uses a mixed method based primarily on respondent preference.[22–24] There was a higher response rate from the Web-based survey compared with the telephone or conventional mail methods, which has also been demonstrated in other studies.[25] In contrast to many other studies, however, successful contact, consent after contact, and

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completion after consent rates were acceptable (56%, 98%, 60%, respectively) given the length of follow-up (mean, 62 months). This is particularly pronounced when compared with other trauma-related quality-of-life outcomes studies, where adequate response rates are often limited to shorter follow-up or smaller prospective cohorts.[26–28] This may be attributable to multiple different arms including the availability of trauma-related data from the JTTR, the reliability of Department of Defense demographics and contact information, as well as the unique familiarity from a team of research nurse coordinators with wartime deployment experience.

There are, however, limitations to this research system. Foremost, the inability to locate, contact, and survey a significant portion of patients with this injury pattern introduces an inherent selection bias. Specifically, lack of outcomes data (either from nonresponse or noncontact) from a number of patients identified from the JTTR query exposes this methodology to a potential hidden burden of morbidity and mortality. This limitation underscores the importance of an interim reappraisal of this methodology, allowing for improvements such as the exploration of additional databases (i.e., Veterans Administration). Another limitation of this research system relates to the use of available survey tools (such as the SMFA and SF-36), which may have limitations when applied to severe combat injuries. Despite these drawbacks, this research system provides a novel foundation for linking injury and its associated management to long-term patient-based outcomes.[15]

CONCLUSION

This study provides a description of methods to provide outcomes data on an injury pattern that has historically been subject to follow-up constraints. The impact of limb salvage should no longer be measured simply in the presence or absence of a limb; rather, it should take into account the impact that the presence of the extremity has on a casualty's life. Nevertheless, although vascular injuries and subsequent outcomes are of critical concern to the combat-wounded patient populations, additional patterns of injury, such as traumatic brain injury and acute lung injury, can be tracked in a similar manner with obvious implications on health care. This novel approach to characterize patient-based outcome measures of functional recovery will provide an insight into the complexities of limb salvage after limb-threatening battlefield vascular injuries. It is hoped that the results of our study will be used to guide individual clinicians, research groups, hospital administrators, and politicians on requirements, resource allocation, and training.

AUTHORSHIP

T.E.R., R.A.I and A.S. conceived and designed this study. A.S., D.J.S. and T.E.R. performed the literature review for the project. A.S., D.J.S., R.A.I., D.L.M., A.C.P and C.A.P. performed the data collection, analysis and organization. A.S., D.J.S., R.A.I. and D.L.M. provided the original drafts of the manuscript, tables and figures with final review and editing performed by S.M.G., L.L.F, D.J.S. and T.E.R.

DISCLOSURE

The authors declare no conflicts of interest.

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